CLAIMS

1. An immunoassay for detecting exposure to *Leishmania* parasites in a subject comprising the steps of:

contacting a sample from the subject suspected of having leishmaniasis with a soluble antigen prepared by utilizing a protein-free medium; and

detecting the presence or measuring the amount of an antibody or fragment thereof in the sample bound to the soluble antigen.

2. The immunoassay of claim 1 wherein the protein-free medium comprises D, xylose.

3. The immunoassay of claim 1 wherein the protein-free medium further comprises at least one of the following ingredients: Hepes buffer, L-glutamine and sodium bicarbonate without phenol red.

4. The immunoassay of claim 1 wherein the antibody is IgG or IgM and is specific for a Leishmania antigen.

5. The immunoassay of claim 1 wherein the sample is a serum sample.

6. The immunoassay of claim 5 wherein the serum sample is modified by diluting it 1:1000 in blocking buffer having 1.0% boiled casein.

7. The immunoassay of claim 1 wherein said immunoassay is capable of diagnosing visceral, cutaneous or canine leishmaniasis in a subject.

8. The immunoassay of claim 1 wherein the *Leishmania* soluble antigen preparation is prepared by using clones of *Leishmania donovani* or *Leishmania mexicana*.

9. An immunoassay for diagnosing leishmaniasis in a subject comprising the steps of:

contacting a sample from the subject with an antibody or fragment thereof that specifically binds the *Leishmania* exo-antigen; and

detecting the presence or measuring the amount of said antibody or fragment thereof bound to said Leishmania exo-antigen.

10. The immunoassay of claim 9 wherein the antibody or fragment thereof is adsorbed onto a substrate.

11. A kit for the diagnosis of leishmaniasis in a subject comprising a substrate and a soluble antigen of either *L. donovani* or *L. mexicana* prepared by utilizing a protein-free medium packaged together for multiple or single use assays.

12. The kit of claim 11 wherein the substrate is coated with the soluble antigen.

13. The kit of claim 11 further comprising a positive control.

14. The kit of claim 11 further comprising a negative control.

15. The kit of claim 11 further comprising a diluent.

16. The kit of claim 11 further comprising an anti-human IgG conjugated to a label.

17. The kit of claim 11 further comprising a substrate chromogen.

18. The kit of claim 11 further comprising a substrate buffer.

19. The kit of claim 11 further comprising a blocking buffer.

20. The kit of claim 11 further comprising a stopping solution.

21. A kit for the detection of an exo-antigen of a leishmania parasite in a sample comprising a fluorescein-labeled antibody that binds the exo-antigen and a counter-stain packaged together for multiple or single use assays.

22. The kit of claim 21 further comprising a protein stabilized buffer solution.

23. The kit of claim 21 further comprising sodium azide.

24. The kit of claim 22 wherein the fluorescein-labeled antibody is diluted in the protein stabilized buffer solution.

25. The kit of claim 21 wherein the counter-stain is Evans Blue.

26. The kit of claim 21 further comprising a solid substrate to which the sample to be tested is fixed.

27. The kit of claim 11 further comprising instructions.

28. The kit of claim 21 further comprising instructions.

29. A diagnostic device comprising a *Leishmania* soluble antigen prepared by utilizing a protein-free medium and a means for detecting an antibody bound to the *Leishmania* soluble antigen.

30. A diagnostic device comprising an antibody or fragment thereof that binds an exo-antigen found in a conditioned medium made by cultivating a *Leishmania* parasite in a protein-free medium.

31. A method of preparing a diagnostic device comprising adsorbing to a substrate an antibody or fragment thereof which binds an exo-antigen found in conditioned medium made by cultivating a *Leishmania* parasite in a protein-free medium.

32. A method of preparing a diagnostic device comprising adsorbing to a substrate a soluble antigen of a *Leishmania* parasite prepared by utilizing a protein-free medium.

33. A method of detecting a *Leishmania* parasite in a sample comprising

contacting the sample with an antibody specific for an exo-antigen found in a conditioned medium made by cultivating the *Leishmania* parasite in a protein-free medium; and

detecting the presence or measuring the amount of an antibody or fragment thereof in the sample bound to an antigen in the sample.

34. A protein-free medium comprising an agent that balances the oncotic pressure across a semi-permeable cell membrane.

35. The protein-free medium of claim 34, wherein the agent is D, xylose.

36. The protein-free medium of claim 34, further comprising at least one of the following ingredients: Hepes buffer, L-glutamine and sodium bicarbonate without phenol red.

37. A method for obtaining an exo-antigen from an organism comprising culturing the organism in a protein-free medium.

38. The method of claim 37, wherein the organism is a leishmania parasite.

39. The method of claim 37, wherein the protein-free medium is XOM.

40. The exo-antigen obtained according to the method of claim 37.